

Case Study: Due Diligence of Contract Manufacturer

The Ask:

The Company, a leading US-based pharmaceuticals company, had procured a new product and was looking for a suitable CDMO to manufacture this new addition to their product portfolio. They required a company that had the capability to not only manufacture their product, but also to perform the Technical Transfer including scale up, manufacture of clinical batches and provide supporting information for filing & registration of this product.

During the Covid 19 pandemic crisis, it was not possible for the client to visit the EU-based site and therefore they requested Primecore to visit the site, on their behalf, and perform due diligence on the CDMO's operation. The timeline was key to making the overall business need date.

The Approach:

Primecore agreed to a clear scope of what was required during the visit and inspection. This included:

- Site Tour
- Assessment of the Management Organisation and Technical Transfer Team
- Review of Material and People Flows
- Overall GMP assessment
- Assessment of Equipment capacity and capability
- High level assessment of systems including data management
- Inspection of Manufacturing Batch Records
- Review of past inspections and associated CAPAs
- Review of Performance metrics
- Review of proposed Technical Transfer timeline and approach

An initial high-level report out was provided following the site visit.

A final report out following a review of additional information provided subsequent to the site visit.

Outcomes:

The rapid visit and inspection by Primecore on the client's behalf provided "the next best thing" to give them immediate confidence that there were no major issues and to proceed with the CDMO contract. The report also provided some follow up recommendations for improvements that will be helpful to the rest of the program.

